Remarks

The 35 U.S.C. 112, first Paragraph Rejection

Claims 1-12 have been rejected as allegedly unpatentable under 35 U.S.C. § 112, first paragraph, as being non-enabled for the prevention of breast cancer. The Examiner, in the Office Action dated February 14, 2008, asserted that the utility of breast cancer prevention with the compounds of Formula I has not been shown either by references provided or data submitted and that undue experimentation would be required to practice the claimed invention.

Applicants respectfully traverse this rejection. Applicants maintain that the prevention of breast cancer is a credible utility that is clear, definite and understood by one skilled in the art. Applicants submit that one skilled in the art understands that the reduction in incidence of breast cancer is prevention of breast cancer.

To illustrate the knowledge of those skilled in the art with respect to the prevention of breast cancer, applicants request that the Examiner review and reconsider the documents submitted in the response filed on June 5, 2005, specifically the Nolvadex® label, "Cancer Facts" and subtitled "Breast Cancer Prevention Studies", "Prevention of Breast Cancer" and "Cancer Facts" and subtitled "Chemoprevention." Applicants respectfully reiterate that these documents show that the prevention of breast cancer is well known to those skilled in the art as the reduction in incidence of breast cancer and is not an incredible utility.

Because the prevention of breast cancer is well known to those skilled in the art, applicants believe that the utility of the presently claimed invention is credible. In addition, Applicants respectfully submit that the compounds of Formula I in the instant claims are useful in reducing the incidence, and thus preventing, breast cancer based upon clinical data that has been obtained.

Lasofoxifene, which is a species of within the genus of Formula I has undergone extensive clinical testing and is currently under review by the FDA for the treatment of osteoporosis. In the 5 year PEARL clinical study it was found that lasofoxifene at a 0.5 mg dose reduced the risk of ER+ (estrogen receptor positive) breast cancer by 67% through 3 years and by 81% through 5 years; reduced the risk of all breast cancer by 65% through 3 years and by 79% through 5 years; reduced the risk of ER+ invasive breast cancer by 73% through 3 years and by 85% through 5 years. Applicants respectfully submit that this data clearly shows that compounds of Formula I are useful in preventing breast cancer in humans.

One of ordinary skill in the art, in view of the guidance provided in the specification, would readily be able to practice the present invention without undue experimentation.

Applicants respectfully request the Examiner to consider the references previously provided, the remarks hereinabove and the data provided above and to withdraw the present rejection of claims 1-12 under 35 U.S.C. §112, first paragraph.

Applicants believe that, in view of the remarks made above and the data provided that this application is in condition for allowance. Reconsideration and allowance of claims 1-12 is respectfully requested.

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